

IN THE MATTER OF	*	BEFORE THE
MAIN STREET FAMILY PHARMACY	*	STATE BOARD OF
RESPONDENT	*	PHARMACY
NON-RESIDENT PHARMACY	*	
PERMIT NO: P05425	*	CASE NO: PI-14-115
* * * * *	*	* * * * *

CONSENT ORDER

On October 14, 2015, the Maryland Board of Pharmacy (“the Board”), pursuant to Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol., 2015 Supp.), charged Main Street Family Pharmacy, permit number P05425 (“Respondent-Pharmacy”), with violating certain provisions of the Maryland Pharmacy Act (“the Act”).

The pertinent provisions of the Act state as follows:

§ 12-703. Operating a pharmacy without a permit.

A person may not establish or operate a pharmacy in this State or a nonresident pharmacy unless the person holds a pharmacy permit issued by the Board.

§ 12-707. Penalties; report of convictions.

...

(e) *Civil penalty.* – (1) Any person who violates ... § 12-703 (“Operating a pharmacy without a permit”) of this title is subject to a civil fine of not more than \$50,000 to be assessed by the Board.

On December 23, 2015, Respondent-Pharmacy appeared (telephonically) before members of the Board for a Case Resolution Conference (CRC) to discuss the potential resolution of the Charges by consent. Thereafter, the Respondent-Pharmacy and the Board agreed to resolve the matter as set forth herein.

FINDINGS OF FACT

The parties agree to stipulate to the following findings of fact as if proven at an evidentiary hearing before the Board:

1. At all times relevant to these charges, Respondent-Pharmacy was located at 126 East Main Street, Newbern, TN 38059.
2. The Respondent-Pharmacy was issued pharmacy Permit No. P05425 to operate a non-resident pharmacy in the State of Maryland on December 15, 2010.
3. The permit expired on December 31, 2011, and was never renewed by Respondent-Pharmacy.
4. An investigation into a separate unlicensed wholesale drug Pharmacy in Maryland led the Board to information that Respondent-Pharmacy was dispensing prescriptions within the state of Maryland without a valid license from January 2012 through May 2013.
5. According to prescription records obtained by the Board, a total of forty-five (45) Maryland patients received compounded drugs from Respondent-Pharmacy during this time period.
6. In total, these prescriptions were valued at \$29,720.17.
7. At no time during January 2012 through May 2013 was Respondent-Pharmacy licensed as a non-resident pharmacy in Maryland.
8. On May 28, 2013, Respondent-Pharmacy announced a voluntary recall of all lots of sterile products compounded by the pharmacy with a use date on or before November 24, 2013. The recall was initiated due to seven reported cases of adverse events in the form of skin abscesses, one of which appeared to be fungal in nature.

9. The Board's investigation also revealed that Respondent-Pharmacy has a history of disciplinary violations in Tennessee, where it is located.
10. Further, the U.S. Food and Drug Administration filed criminal and civil actions against Respondent-Pharmacy and the company's co-owners, David A. Newbaker and Christy Newbaker.
11. In December 2014, Mr. Newbaker and Respondent-Pharmacy each pleaded guilty to a misdemeanor criminal violation of the federal Food, Drug and Cosmetic ("FD&C") Act.
12. Mr. Newbaker was sentenced to 12 months of probation, and both Mr. Newbaker and Respondent-Pharmacy were ordered to pay a fine of \$25,000.
13. Ms. Newbaker entered into a civil consent decree that imposed a permanent injunction against Respondent-Pharmacy, prohibiting the pharmacy from manufacturing, holding and distributing drug products until the company complies with the FD&C Act and its regulations, among other requirements.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that Respondent-Pharmacy violated § 12-703 of the Act by dispensing prescriptions within the state of Maryland without maintaining a valid permit.

ORDER

Based on agreement of the parties, it is hereby:

ORDERED that Respondent-Pharmacy shall pay a fine in the amount of \$25,000, which amount shall be **STAYED**, subject to its compliance with the terms of this agreement and the provisions of the Maryland Pharmacy Act; and it is further

ORDERED that Respondent-Pharmacy shall now and forever **CEASE AND DESIST** from dispensing drugs in Maryland; and it is further

ORDERED that Respondent-Pharmacy shall not apply for nor receive a pharmacy permit in Maryland that is owned by David Newbaker, Christy Newbaker or in substantial part by any of their family members; and it is further

ORDERED that neither David Newbaker nor Christy Newbaker shall apply for nor receive individual pharmacist licenses in Maryland; and it is further

ORDERED that failure to comply with the terms and conditions of this Consent Order, constitutes a violation of this Consent Order and the Board, in its discretion, after notice and an opportunity for a hearing before the Board, shall impose a \$25,000 fine and may impose any other appropriate sanction under the Act; and it is further

ORDERED that Respondent-Pharmacy shall bear all expenses associated with this Order, and it is further

ORDERED that this document constitutes a formal disciplinary action of the State Board of Pharmacy and is therefore a public document for purposes of public disclosure pursuant to the Public Information Act, Md. Code Ann., Gen. Prov. § 4-101 *et seq.* (2014 & 2015 Repl. Vol.).

2/17/16
Date

David G. Jones, P.D. SEC REC'D
Mitra Gavgani, P.D., President DAVID JONES
State Board of Pharmacy
in behalf of
Mitra Gavgani, President
PRESIDENT

CONSENT

David Newbaker and Christy Newbaker, co-owners of Main Street Family Pharmacy, acknowledge that we have had the opportunity to consult with legal counsel before signing this document. By this Consent, we accept on behalf of Main Street Family Pharmacy, to be bound by this Consent Order and its conditions and restrictions. On its behalf, we waive any rights we may have had to contest the Findings of Fact and Conclusions of Law.

We acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which Main Street Family Pharmacy would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf and to all other substantive and procedural protections as provided by law.

We acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. We also affirm that we are waiving Main Street Family Pharmacy's right to appeal any adverse ruling of the Board that might have followed any such hearing.

We sign this Consent Order without reservation, and we fully understand and comprehend the language, meaning and terms of this Consent Order. We voluntarily sign this Order on behalf of Main Street Family Pharmacy and understand its meaning and effect.

2/11/16
Date



David Newbaker, Co-owner
Main Street Family Pharmacy

Christy Newbaker

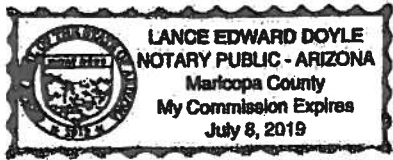
2-11-2016
Date

Christy Newbaker, Co-owner
Main Street Family Pharmacy

NOTARY

STATE OF Arizona
COUNTY/CITY OF Maricopa:

I hereby certify that on this 11 day of February, 2016, before me, a Notary Public of the State of Arizona and County/City aforesaid, personally appeared **DAVID NEWBAKER and CHRISTY NEWBAKER**, and made an oath in due form that the foregoing Consent was their voluntary act and deed.



[Signature]
Notary Public
My commission

expires: 07/08/19
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